PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61F 2/08	A1	(11) International Publication Number: **WO 90/12550** (43) International Publication Date: 1 November 1990 (01.11.90)

(21) International Application Number: PCT/FI90/00113

(22) International Filing Date: 24 April 1990 (24.04.90)

(30) Priority data:
891973 26 April 1989 (26.04.89) FI

(71) Applicant *(for all designated States except US)*: BIOCON OY [FI/FI]; Runeberginkatu 3 A 1, SF-33710 Tampere (FI).

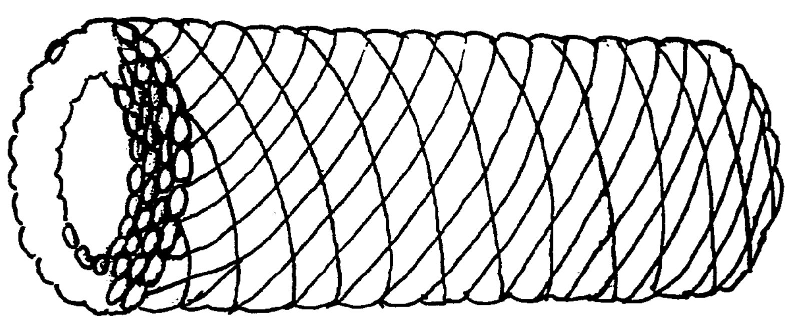
(72) Inventors; and
(75) Inventors/Applicants *(for US only)* : TÖRMÄLÄ, Pertti [FI/FI]; Runeberginkatu 3 A, SF-33710 Tampere (FI). POHJONEN, Timo [FI/FI]; Nosturinraitti 2 B 17, SF-33720 Tampere (FI). HELEVIRTA, Pertti [FI/FI]; Ojavainionkatu 10 A 4, SF-33710 Tampere (FI). VAINIONPÄÄ, Seppo [FI/FI]; Orapihlajatie 21-27 B 12, SF-00320 Helsinki (FI). TAMMINMÄKI, Markku [FI/FI]; Kukkolankatu 23 B 12, SF-33400 Tampere (FI). ROKKANEN, Pentti [FI/FI]; Marjaniemenranta 29, SF-00930 Helsinki (FI). PARTIO, Esa [FI/FI]; Lauttasaarentie 43 A 18, SF-00200 Helsinki (FI).

(74) Agent: KAHILAINEN, Hannu; Tampereen Patenttitoimisto Oy, Kanslerinkatu 6, SF-33720 Tampere (FI).

(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.

(54) Title: SELF-REINFORCED SURGICAL MATERIALS AND DEVICES



(57) Abstract

This invention describes self-reinforced, absorbable surgical materials and/or implants and/or their parts and/or components, which can be implanted into the living tissue or on its surface for the purpose of e.g. to repair tissue damages, to join tissues or their parts to each other, to augment tissues or their parts, to separate tissues or their parts from each other and/or from their surroundings, and/or to conduct material between tissues or their parts and/or out of tissues or from the outside into the tissues, for which self-reinforced materials and/or implants or their parts and/or components is characteristic that their reinforcing elements are wound at least partially around some axis penetrating the implant. These implants have better and more isotropic strength properties than the known self-reinforced implants.

+ See back of page

DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**ES**	Spain	**MC**	Monaco
AU	Australia	**FI**	Finland	**MG**	Madagascar
BB	Barbados	**FR**	France	**ML**	Mali
BE	Belgium	**GA**	Gabon	**MR**	Mauritania
BF	Burkina Fasso	**GB**	United Kingdom	**MW**	Malawi
BG	Bulgaria	**GR**	Greece	**NL**	Netherlands
BJ	Benin	**HU**	Hungary	**NO**	Norway
BR	Brazil	**IT**	Italy	**RO**	Romania
CA	Canada	**JP**	Japan	**SD**	Sudan
CF	Central African Republic	**KP**	Democratic People's Republic of Korea	**SE**	Sweden
CG	Congo			**SN**	Senegal
CH	Switzerland	**KR**	Republic of Korea	**SU**	Soviet Union
CM	Cameroon	**LI**	Liechtenstein	**TD**	Chad
DE	Germany, Federal Republic of	**LK**	Sri Lanka	**TG**	Togo
DK	Denmark	**LU**	Luxembourg	**US**	United States of America

Self-reinforced surgical materials and devices

In surgery it is known to use implants or their parts or components, which are manufactured at least partially of an absorbable polymer and/or of a polymer composite containing reinforcing elements, for fixation of bone fractures, osteotomies or arthrodeses, joint damages, tendon and ligament damages etc. Such implants are e.g. rods, screws, plates, intramedullary nails and clamps, which have been described in the professional literatures of material technique and medicine.

U.S. Pat. No. 3 620 218, E. Schmitt and R. Polistina "Cylindrical Prosthetic Devices of Polyglycolic Acid" and U.S. Pat. No. 3 739 733, E. Schmitt and R. Polistina "Polyglycolic Acid Prosthetic Devices" describe implants like rods, screws, plates and cylinders which have been manufactured of polyglycolic acid.

U.S. Pat. No. 4 052 988, N. Doddi, C. Versfelt and D. Wasserman "Synthetic Absorbable Surgical devices of Polydioxanone" describes absorbable sutures and other surgical devices manufactured of polydioxanone.

U.S. Pat. No. 4 279 249, M. Vert, F. Chabot, J. Leray and P. Christel "New Prosthesis Parts, Their Preparation and Their Application" describes osteosynthesis devices which have been manufactured of polylactide or of copolymer containing plenty of lactide units, which matrix has been reinforced with reinforcing elements which have been manufactured of polyglycolide or of copolymer including mainly glycolic acid units.

DE 29 47 985 A 1, S. Belych, A. Davydov, G. Chromov, A. Moscenskij, I. Movsovic, G. Rojtberg, G. Voskresenskij, G. Persin and V. Moskvitin "Biodestruktiver Stoff für Verbindungselemente für Knochengewebe" describes at least partially degradable composites which comprise e.g. a

copolymer of methylmethacrylate and N-vinylpyrrolidone, which has been reinforced with polyamide fibres or with oxycellulose fibres.

U.S. Pat. No. 4 243 775, M. Rosensaft and R. Webb "Synthetic Polyester Surgical Articles" describes surgical products manufactured of copolymer of glycolic acid and trimethylene carbonate.

U.S. Pat. No. 4 329 743, H. Alexander, R. Parsons, I. Strauchler and A. Weiss "Bioabsorbable Composite Tissue Scaffold" describes a composite of a bio-absorbable polymer and carbon fibres, which composite is suitable for manufacturing surgical articles.

U.S. Pat. No. 4 343 931, T. Barrows "Synthetic Absorbable Devices of Poly(esteramides)" describes absorbable polyesteramides, which are suitable for manufacturing of surgical implants.

Pat. Appl. EPO 0 146 398, R. Dunn and R. Casper " Method of Producing Biodegradable Prosthesis and Products therefrom" describes a method for manufacturing of biodegradable prostheses about biodegradable polymer matrix which is reinforced with biodegradable ceramic fibres.

WO 86/00533, J. Leenslag, A. Pennings, R. Veth and H. Jansen "Bone Implant" describes an implant material for reconstructive surgery of bone tissue, which material comprises a biodegradable porous polymer material and biodegradable or biostable fibres.

The publication D. Tunc "A High Strength Absorbable Polymer for Internal Bone Fixation", 9th Annual Meeting of the Society for Biomaterials, Birmingham, Alabama, April 27 - May 1, 1983, p. 17, describes a high strength absorbable polylactide, with an initial tensile strength about 50-60 MPa and which material retains a significant part of its initial strength

8-12 weeks after the implantation. This material can be considered suitable to be applied as basic material in manufacturing of internal bone fixation devices which are totally absorbable in living tissues.

The publication D. Tunc, M. Rohovsky, W. Lehman, A. Strogwater and F. Kummer "Evaluation of Body Absorbable Bone Fixation Devices", 31st Annual ORS, Las Vegas, Nevada, Jan. 21-24, 1985, p. 165, describes high strength, totally absorbable polylactide (initial strength 57,1 MPa), which was used as plates and screws for fixation of canine radial osteotomies.

The publication D. Tunc, M. Rohovsky, J. Zadwadsky, J. Spieker and E. Strauss "Evaluation of Body Absorbable Screw in Avulsion Type Fractures", The 12th Annual Meeting of the Society for Biomaterials, Minneapolis - St. Paul, Minnesota, USA, May 29 to June 1, 1986, p. 168, describes the application of high strength polylactide screws in fixation of avulsion-type fractures (fixation of canine calcaneous osteotomy).

U.S. Pat. No. 4 776 329, R. Treharne "Resorbable Compressing Screw and Method", describes a compression screw equipment comprising a non-absorbable compression parts and a screw. At least the head of the screw comprises material, which is resorbable in contact with tissue fluids.

Self-reinforced absorbable fixation devices have significantly higher strength values than the non-reinforced absorbable fixation devices. U.S. Pat. No. 4 743 257, P. Törmälä, P. Rokkanen, J. Laiho, M. Tamminmäki and S. Vainionpää "Material for Osteosynthesis Devices", describes a self-reinforced surgical composite material, which comprises an absorbable polymer or copolymer, which has been reinforced with absorbable reinforcing elements, which have the same chemical element composition as the matrix.

FI Pat. Appl. No. 87 0111, P. Törmälä, P. Rokkanen, S. Vainionpää, J. Laiho, V.-P. Heponen and T. Pohjonen "Surgical

Materials and Devices", describes self-reinforced surgical bone fracture fixation devices which have been manufactured at least partially of fibrillated absorbable material(s).

According to the publication T. Pohjonen, P. Törmälä, J. Mikkola, J. Laiho, P. Helevirta, H. Lähde, S. Vainionpää and P. Rokkanen "Studies on Mechanical Properties of Totally Biodegradable Polymeric Rods for Fixation of Bone Fractures", VIth International Conference PIMS, Leeuwenhorst Congress Centre, Holland, 12-14 April 1989, p. 34/1-34/6, self-reinforced absorbable surgical materials have excellent strength properties, e.g. SR-polyglycolide had bending strength 415 MPa and SR-polylactide 300 MPa.

Also in the publication D. Tunc and J. Jadhav "Development of Absorbable Ultra High Strength Polylactide", Am. Chem. Soc., 196th ACS Meeting, Abstracts of Papers, L.A., California, Sept. 25-30, 1988, p. 383-387, a good tensile strength (300 MPa) for fibrillated SR-polylactide was measured.

The publication E. Partio, O. Böstman, S. Vainionpää, H. Pätiälä, E. Hirvensalo, K. Vihtonen, P. Törmälä and P. Rokkanen "The Treatment of Cancellous Bone Fractures with Biodegradable Screws", Acta Orthop. Scand., 59(5), 1988, p. 18, describes the fixation of cancellous bone fractures with self-reinforced absorbable screws, which have a flat head, which head can be located to a slot at the tip of the screwdriver in order to drive the screw into a channel made into the bone.

Although the known self-reinforced absorbable surgical composites have certain good mechanical strength properties, they have the disadvantage that the mechanical strength properties are strongly anisotropic. Because the known self-reinforced absorbable composites, which have been manufactured e.g. with the sintering technique or with fibrillation (drawing) technique, are parallel reinforced, the binding forces between the reinforcing elements are determined by

the strength of the matrix and of the boundary surface between matrix and reinforcing elements. The parallel reinforcing means here that reinforcing elements, like fibres, threads, fibrils or bundles of them form parallel structures into the matrix.

Typically the tensile strength of the reinforcing elements is hundreds or thousands of MPa, but the internal strength of the matrix and of the matrix - reinforcing element boundary is only the order of magnitude of 10-100 MPa. As a consequence of this structural anisotropy the fracture of self-reinforced absorbable composites occurs relatively easily as the delamination between the parallel reinforcing element layers or between the parallel reinforcing elements, when the external forces affect to the implant from such a direction that the reinforcing elements cannot carry those external forces. Accordingly, the delamination means the fracture of the composite material along the matrix between the reinforcing elements or along the boundary surface between the matrix and the reinforcing elements.

In this invention we have found unexpectedly that in such a self-reinfoced absorbable surgical material or implant (device) or its part and/or component, where the reinforcing elements have been twisted at least partially around some axis which penetrates the implant, the tendency to the fracture by means of the delamination has been almost completely eliminated or it has at least significantly reduced when compared to the fracture behaviour of known self-reinforced absorbable materials and implants.

This invention describes self-reinforced, absorbable surgical materials and/or implants and/or their parts and/or components, which can be implanted into the living tissue or on its surface for the purpose of e.g. to repair tissue damages, to join tissues or their parts to each other, to augment tissues or their parts, to separate tissues or their parts from each other and/or from their surroundings, and/or

to conduct material between tissues or their parts and/or out of tissues or from the outside into the tissues, for which self-reinforced materials and/or implants or their parts and/or components is characteristic that their reinforcing elements are wound at least partially around some axis penetrating the implant.

The reinforcing elements can be typically oriented molecular chains, molecule chain groups or their parts, oriented crystalline lamellae or spherulites, fibrils or their parts or corresponding morphological structural elements. They can also be fibres, filaments, film fibres, threads, braids, non-vowen structures, networks, meshes, knits or vowen structures or corresponding.

Because the reinforcing elements do not form in the materials of the invention coherent straight planar structures, the delamination surfaces in the materials of the invention are at least partially curved and/or partially or completely eliminated depending on in which way the reinforcing elements have been wound around some axis penetrating the implant. As a consequence the materials of the invention have more isotropic strength properties than the known self-reinforced absorbable materials and implants have. Therefore the implants of the invention have a better reliability in operation and they have more many-sided applications than the known implants have.

According to a specially advantageous embodiment the invented implants, their parts or components contain at least one hole, hollow or cavity, around which the reinforcing elements have been wound at least partially. Such implants have several advantages in comparison to the known ones. When the implant contains a hole, hollow or cavity or corresponding, the mass of the implant is smaller than the mass of the solid implant. This means advantageously a smaller amount of foreign material in the tissues of the patient in the former case. A hole, hollow or cavity increases also the surface area of the

implant which accelerates its hydrolysis in living tissues. A hollow inside of the implant can be used also to guide the implant into the tissue e.g. with a suitable guiding device. Additionally, a metallic rod, wire etc. which has been pushed into the hole, hollow or cavity, can act as an x-ray positive probe, which shows during the operation the exact position of the implant in the tissues. It is also possible to use the long hole or cavity inside of a self-reinforced absorbable screw of the invention as the screwdriver socket during the implantation of the screw by inserting the tip of the screwdriver into the hole so that the torque force from the screwdriver is divided along the screw axis. As a consequence of spiral orientation such screws resist clearly higher torque forces than the known parallel fibre reinforced or non-reinforced absorbable screws because the torque force is received as tensile stresses by the wound reinforcing elements which typically have very high tensile strength. In the known non-reinforced and self-reinforced screws the torque forces are received by the screw material mainly as shear forces.

According to an advantageous embodiment the implant of the invention is an intramedullary nail, which is at least partially hollow and where the reinforcing elements have been wound at least partially around the long axis of the intramedullary nail. The cross-sectional form of such an intramedullary nail can be e.g. a circle, an ellipse, a triangle, a quadrangle, a polygone or like a four-leaved clover, kidney-like etc. Figure 1 shows some typical embodiments of the cross-sectional form of the intramedullary nail. It is self-evident that also other forms of the cross-section than those given in Figure 1 can be applied in the intramedullary nails of the invention.

According to an advantageous embodiment the wall the intramedullary nail contains at least one elongated groove or hole, which has been formed by bending the wall of the intramedullary nail inside or by splitting it at least

partially or by making at least one hole into the wall of the implant. The elongated groove or hole(s) give to the intramedullary nail flexibility in such an amount that the intramedullary nail does not split easily the bone, when the intramedullary nail is hammered into a tight drill hole inside of the bone. Figure 2 shows typical cross-sectional forms of intramedullary nails, which have in their wall a groove, a fissure or holes to increase its flexibility.

Figure 3 shows some examples in perspective view of intramedullary nails of the invention. On the surface of the intramedullary nail of Figure 3a spirally oriented lines have been drawn, describing the orientation of reinforcing elements.

The intramedullary nails can include also holes through which they can be fixed into bone e.g. with screws as is shown schematically in a cross-sectional Figure 3e.

The fixation devices of the invention can be manufactured of absorbable (biodegradable or resorbable) polymers, copolymers, polymer mixtures or composites which have been described in many publications, like e.g. in the following inventions: U.S. Pat. No. 3 297 033, U.S. Pat No. 3 636 956, U.S. Pat. No. 4 052 988, U.S. Pat. No.4 343 931, U.S. Pat. No. 3 969 152, U.S. Pat. No. 4 243 775, FI Pat. Appl. No. 85 5079, FI Pat. Appl. No. 86 0366, FI Pat. Appl. No. 86 0440 and FI Pat. Appl. No. 88 5164.

Table 1 gives some known biodegradable polymers, which can be used as such or as mixtures as raw materials of the implants of the invention both as matrix material (as a binding polymer) and/or as reinforcing elements.

Table 1. Absorbable polymers

1. Polyglycolide (PGA)

<u>Copolymers of glycolide</u>:
2. Glycolide/L-lactide copolymers (PGA/PLLA)
3. Glycolide/trimethylene carbonate copolymers (PGA/TMC)

Polylactides (PLA)

<u>Stereocopolymers of PLA</u>:
4. Poly-L-lactide (PLLA)
5. Poly-DL-lactide (PDLLA)
6. L-lactide/DL-lactide copolymers

<u>Copolymers of PLA</u>:
7. Lactide/tetramethylglycolide copolymers
8. Lactide/trimethylene carbonate copolymers
9. Lactide/δ-valerolactone copolymer
10. Lactide/ε-caprolactone copolymer
11. Polydepsipeptides
12. PLA/polyethylene oxide copolymers
13. Unsymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones

14. Poly-ß-hydroxybutyrate (PHBA)
15. PHBA/δ-hydroxyvalerate copolymers (PHBA/HVA)

16. Poly-ß-hydroxypropionate (PHPA)
17. Poly-p-dioxanone (PDS)
18. Poly-δ-valerolactone
19. Poly-ε-caprolactone
20. Methylmethacrylate-N-vinyl pyrrolidine copolymers
21. Polyesteramides
22. Polyesters of oxalic acid
23. Polydihydropyrans
24. Polyalkyl-2-cyanoacrylates
25. Polyurethanes (PU)
26. Polyvinylalcohol (PVA)
27. Polypeptides
28. Poly-ß-malic acid (PMLA)
29. Poly-ß-alkanoic acids
30. Polyvinylalcohol (PVA)
31. Polyethyleneoxide (PEO)
32. Chitine polymers

Reference: S. Vainionpää, P. Rokkanen and P. Törmälä, <u>Progr. Polym. Sci.</u>, <u>14</u>, 1989, p. 679-716.

It is self-evident that also other absorbable polymers than those given in Table 1 can be applied in manufacturing the devices or their parts of this invention. E.g. the following

publications give absorbable (biodegradable) polymers which can be applied in this connection: U.S. Pat. No. 4 700 704, U.S. Pat. No. 4 653 497, U.S. Pat. No. 4 649 921, U.S. Pat. No. 4 559 945, U.S. Pat. No. 4 532 928, U.S. Pat. No. 4 605 730, U.S. Pat. No. 4 441 496, U.S. Pat. No. 4 435 590 and U.S. Pat. No. 4 559 945.

The implants of the invention can be manufactured of absorbable polymers or copolymers by using one polymer or polymer mixture. The devices can be reinforced in addition to self-reinforcing also with fibres which are manufactured of other resorbable polymer or polymer mixture or with fibres which are manufactured of a resorbable ceramic material (like with ß-tricalciumphosphate fibres or with CaAl-fibres; see e.g. EPO Appl. 146 398) and/or with biostable fibres like glass-, carbon- or polymeric fibres.

The devices of the invention can contain also layered parts comprising e.g. (a) a flexible surface layer which increases the toughness of the implant and/or acts as a hydrolysis barrier and (b) a stiff inner layer.

The surgical devices of the invention can be manufactured of absorbable polymers and of possible absorbable and/or biostable reinforcing fibres by means of different methods like with methods known in plastics technology. Such methods are e.g. injection moulding, extrusion as such or combined with fibrillation and forming (see e.g. FI Pat. Appl. No. 87 0111) or compression moulding, where the samples are formed from the raw materials by means of heat and/or pressure.

The devices of the invention can be manufactured from the above raw materials also by means of so called solution techniques. Here at least part of the polymer is dissolved in a suitable solvent or it is plasticized with a solvent and the material or material mixture is compressed to a device or preform by means of pressure and possibly applying heat, so that the dissolved or plasticized polymer glues the

material to a macroscopical sample, from which the solvent can be removed by evaporation.

It is natural that the devices of the invention can include additionally different kind of additives or auxiliary materials to facilitate the processing of the material (e.g. stabilizators, antioxidants or plasticizers) or to change its properties (e.g. plasticizers or powder-like ceramic materials or biostable fibres like polyaramide-or carbon fibres), or to facilitate its use (e.g. colours).

According to one advantageous embodiment the devices of the invention contain some bioactive material or materials, like antibiotic or chemotherapeutic additives facilitating the healing of the wound, growth hormone, antifertilization additive, anticoagulant (like heparine) etc. Such bioactive implants are especially advantageous in clinical use, because they have in addition to the mechanical function also biochemical, medicinal etc. effects in different tissues.

Because the materials of the invention have good mechanical properties, they can be processed mechanically into different forms. E.g. the plate preforms can be rolled, compressed, stamped, upset, bent etc. either when cooled to a temperature below the room temperature or at the room temperature or at an elevated temperature. They can be processed also by drilling, grinding, milling etc. or with other methods of mechanical processing or by other methods like laser processing or water jet cutting or ultra sound cutting. The rods and tubes of the invention can be processed also with the corresponding methods. E.g. it is possible to roll threads on the surface of a rod or a tube by rolling a rod or a tube between rotating (possibly heated) rolls (usually 2-3 rolls) which rolls have been grooved in a suitable way. This kind of rolling of the threads is in a common use in metal industry, but so far, this method has not been applied in the processing of absorbable polymeric materials. It is possible also to upset a head to the rod, and rods can be

wound to helices, bent to clamps etc.

The invention and its function has been illustrated with the following non-limiting examples.

Example 1.

Polyglycolide surures (Dexon[R]; size 2 USP, manufacturer Davis+Geck, England) were collected to a parallel thread bundle and the bundle was wound around its long axis in such way that the threads were wound in relation to the long axis of the thread bundle to an angle of 45° (Figure 4a shows schematically the parallel thread bundle and Figure 4b the wound thread bundle). The wound thread bundle was located into a cylindrical compression mould (length 70 mm, diameter 3.2 mm) and it was sintered (T = 218°C, time 5 min, pressure 2000 bar) to a self-reinforced rod, where the reinforcing elements (threads) were wound around the long axis of the rod (a spiral reinforced rod). The rod is shown in Figure 4c which shows also schematically the orientation of reinforcing threads. As a comparison material a corresponding rod was manufactured by sintering a parallel thread bundle to a rod.

The torsional load carrying capacity of the spiral reinforced rod was measured by fixing the ends of the rod into a torsional strength measurement device and by winding the other end of the rod in the same direction where the spiral reinforcement had been wound in the rod. As a comparison the torsional load carrying capacity of the parallel thread reinforced rods was measured. The maximum force of torsional load was for spiral reinforced rods 18 N and for parallel thread reinforced rods 10 N.

Example 2.

Melt spinning and (hot) drawing method was applied to manufacture fibres of the following absorbable polymers: poly-L-lactide (Mw 260 000, L-lactide/D-lactide copolymer

(molar ratio 90/10), glycolide/lactide copolymer (molar ratio 90/10) and poly-ß-hydroxy butyrate (Mw ca. 700 000). The polymers were manufactured by Boehringer/Ingelheim (Germany), CCA biochem (Holland) and ICI (England).

According to the principles of Example 1 the above fibres were applied to manufacture spiral reinforced and parallel reinforced absorbable (self-reinforced) rods by the sintering technique. The torsional load carrying capacity of each rod was measured according to the method of Example 1. The torsional load carrying capacities of the spiral oriented rods were 1.3-2 times higher than those of parallel fibre reinforced rods.

Example 3.

Dexon^R -sutures (size USP 1) were applied to manufacture absorbable, self-reinforced screws with the following dimensions: the total length 120 mm, the diameter of the screw core 6 mm, the length of the threaded part 20 mm (in the tip of the screw), the maximum thread diameter 8 mm, the maximum diameter of the head 9 mm. The screws were manufactured by sintering Dexon sutures in a hydraulic screw mould. The sintering coditions were: T = 215-225°C, the compression time 10 min and the pressure 2000 bar.

Two types of screws were manufactured:

A) Screws with the structure of the invention were manufactured by winding Dexon suture (size USP 1) around a rotating, polished metallic (steel) mandrel with the filament winding techniques by changing the winding angle between-60° - 0° - +60°, where 0° = the direction perpendicular to the long axis of the mandrel and ±60° = the maximum and the minimum values of the winding angle on the both sides of the perpendicular direction. The length of the mandrel was 140 mm. The maximum thickness of the mandrel was 3 mm at the one end and 2 mm at the other end. The cross-section of the

mandrel was a square. The filament wound preform was cut to the length of 125 mm and it was sintered to a headless screw preform with the 20 mm long thread part at its tip leaving the metal mandrel inside of the screw preform. The above screw mould was applied. The head was upset with the compression moulding technique to the other end of the screw preform (to the end where the metal mandrel was thicker). The screw head was upset in such a way that the metal mandrel was uncovered 5 mm. The metal mandrel was drawn out of the screw, which left inside of the screw a square hole penetrating the screw.

B) Corresponding screws were manufactured of Dexon parallel thread bundles, where the reinforcing elements (Dexon^{R} threads) were oriented parallel with the long axis of the screw.

The torsional load carrying capacity of the spiral oriented screw was measured by pushing into the hole inside of the screw a long tip of a screwdriver which fitted tightly into the hole. The handle of the screwdriver and the tip of the thread part of the screw were fixed to the torsional strength measurement apparatus and the torsional load carrying capacity was measured by winding the handle of the screwdriver around its long axis until the screw broke. A similar measurement was done for parallel thread reinforced screws. The torsional load carrying capacity of the spiral reinforced screws was 1.6 times higher than that of the parallel thread reinforced screws.

Example 4.

Linen weave type fabric was woven of glycolide/lactide sutures (Vicryl^{R}, size 1 USP) by using Vicryl sutures both as warp and weft yarns. The fabric was rolled up to a ca. 8 mm thick and 40 mm long roll, which was flattened to a 5 mm thick flat roll which was pushed into a compression mould cavity with dimension 5 x 15 x 40 mm which was open from one long, narrow

side. A suitable rectangular steel plate was compressed on the fabric roll, the mould was evacuated and the fabric was sintered at ca. 180°C (time 10 min, pressure 2000 bar) to a self-reinforced rod with dimensions 5 x 5 x 40 mm and with a square cross-section. A layered rod was made for comparison by filling the mold with (5 x 40 mm) Vicryl fabric strips and by sintering them together.

Figure 5a shows schematically a rod according to the invention. Here a spiral orientation of the fabric has been described with a thick spiral line at the end of the rod and the positions of the warp and weft yearns on the surface of the rod have been described with thin lines. Figure 5b shows the corresponding layered rods with the fabric layers in a vertical position. (During the compression of this rod the fabrics were in a horizontal position.)

5 mm long parts were milled from the rods and they were cast partially into epoxy plastic (EP) according to the schematic side views of Figures 5c and 5d. The shear strength of the material of the invention (Figure 5c) and the shear strength of the layered material in the direction of the plane of the layers (Figure 5d) was measured by loading the partially into the epoxy cast samples in the direction given by the arrow. The measurements gave for the shear strength of the material of the invention the value of 80 MPa and for the layered material the value of 45 MPa.

Spiral reinforced rods and layered rods were split by sawing in the direction of their long axis. The layered rods were split in the plane of the fabrics. Accordingly spiral reinforced rods shown schematically in Figure 5e and layered rods (Figure 5f) were obtained. The layered rod which is seen in Figure 5f has been wound 90° around its long axis after splitting if compared to the rod of Figure 5b. The rods were hydrolyzed 3 weeks in distilled water (T = 37°C) and their bending strengths were measured with three point bending method by supporting the rods from their both ends and by

loading them in the middle of the rod (shown by arrows in Figures 5e and 5f). The details of the bending test arrangements are given in the publication P. Törmälä et al. "Ultra high strength absorbable self-reinforced polyglycolide (SR-PGA) composite rods for internal fixation of bone fractures: in vitro and in vivo study", J. Biomed. Mater. Res., in press. The bending strength of the hydrolysed rods of the invention was 40 MPa and of the layered rods 25 MPa.

Example 5.

Compression moulding technique was applied to manufacture of poly-L-lactide (Mw ca. 700 000, manufacturer CCA biochem, Holland) 5 mm thick plates, which were drawn and rolled at an elevated temperature (rolling temperature > 90°C) to 0.4 mm thick films. A 30 mm wide piece of the film was heated to ca. 90°C and rolled according to Figure 5a to a roll which was sintered to a spiral oriented rod with dimensions 5 x 5 x 30 mm in the mould of Example 4 at temperature 175°C.

The layered rod according to Figure 5 b was manufactured by filling the cavity of the mould of Example 4 with 5 x 30 mm big strips which were cut from the drawn and rolled film.

Analogously with the tests described in Figures 5c and 5d the shear strength of the spiral oriented and of the parallel film oriented rod was measured. The shear strength of the spiral oriented rods was 120 MPa and of the parallel oriented material 40 MPa.

Example 6.

Poly-L-lactide (Mw ca. 260 000, manufacturer Boehringer/Ingelheim, Germany) was extruded to a cylindrical preform with diameter of 4 mm. The extruded preform was drawn through a conical die (conical angle of the die 25°, length of the die 25 mm). The diameter of the circular hole at the tip of the die was 2.6 mm. The drawing was done at a

temperature between the glass transition temperature (T_g) and the melting temperature (T_m) of the polymer. Typical drawing temperatures were between 90°C and 150°C. The drawing was repeated for the drawn prefom by using an other die with the hole tip diameter of 1.2 mm. The final self-reinforced (parallel fibre reinforced) rod had the diameter of 1.15 mm. The rod was cut into 20 mm long pieces. Part of the rods were transformed to spiral reinforced by winding the ends of the rods at the opposite directions at 90°C tempereature so that the final orientation of the reinforcing fibrils deviated ca. 45° from the direction of the long axis of the rod. The torsional load resistance of spiral reinforced and parallel reinforced rods was measured at room temperature. The spiral reinforced rods had about 1.4 times higher torsional load carrying capacity in comparison to the parallel fibre-reinforced rods, when the spiral oriented rods were loaded in the same direction where the spiral reinforcement was oriented.

Example 7.

A. Parallel fibre reinforced, self-reinforced cylindrical polylactide rods were manufactured by sintering poly-L-lactide (PLLA) fibres (Mw 700 000, T_m ca. 180°C) and L-lactide/D-lactide (PLDLA) copolymer fibres (molar ratio L-lactide/DL-lactide = 90/10, T_m of the fibres = 150°C) together at T = 175°C in such a way that PLDLA-fibres melted and wetted PLLA-fibres (PLDLA formed the binding matrix around the PLLA-fibres). The dimensions of the rods were: the length 60 mm, the diameter 4.8 mm.

B. Self-reinforced polylactide preforms were manufactured by the filament winding technique by winding PLLA-fibres and PLDLA-fibres (weight ratio 1:1) around a cylindrical mandrel (diameter 3.8 mm) and by sintering the preforms in a cylindrical mould (sintering temperature = 175°C) into cylindrical tubes with the outer diameter of 4.8 mm. The mandrel was removed from the inside of the tube and another

mandrel was pushed into the hole inside of the tube. This mandrel had a longitudinal 1 mm deep and broad groove on its surface. A schematic cross-sectional Figure 6a shows the self-reinforced tube and the mandrel, which has a longitudinal groove. The tube was heated to 110°C and it was deformed with a heated tool so that part of the tube wall yielded into the groove of the mandrel according to the Figure 6b. The tube was cooled to the room temperature, the tool and the mandrel were removed giving an intramedullary nail according to the Figure 6c.

The application of the grooved tubes (see Figure 6c) and of the comparative solid rods as intramedullary nails were tested with 20 femurs of rabbits. A drill hole with the length of 60 mm and diameter of 4.5 mm was drilled into each femur from their proximal end. The dircetion of the drill hole was parallel with the long axis of the femur. Solid intramedullary rods of paragraph A were tapped into the drill hole of 10 femurs. An intramedullary nail according to paragraph B was tapped into the drill hole of other 10 femurs. 2 of the femurs split when the solid rods were tapped into the drill holes. The tapping of the hollow, grooved intramedullary nails into the drill holes occurred without problems in all cases.

Example 8.

Dexon^R sutures (size 1 USP) were braided to three-dimensional cylindrical, longitudinal braid by so called 3-D technique (Figure 7 gives schematically the location of the Dexon sutures in the braid structure). The thickness of the braid was ca. 6 mm. The braid was sintered in a cylindrical screw mould into self-reinforced screws (the length of the fully threaded screw was 40 mm, with maximum diameter of the head 8 mm, maximum thread diameter 4.5 mm, and minimum thread diameter 3.2 mm). Sintering conditions were: T =208-215°C, time = 10 min, pressure = 2000 bar.

Corresponding screws were manufactured of Dexon sutures by filling the mould cavity with parallely oriented Dexon threads and by sintering them to screws.

The torsional strengths of the screws were measured.

The 3-D braided screws of the invention showed the torsional strength of 1.4 NM. The parallel thread reinforced screws showed the torsional strength of 0.8 NM.

Example 9.

3-D braided preforms were manufactured according to Example 8 of PLLA-fibres and of PLDLA-fibres (weight ratio 1:1). The preforms were sintered in a cylindrical mould to 120 mm long and 2.6 mm diameter rods at the temperature 175°C. A 20 mm long thread (maximum thread diameter 3.2 mm) was rolled to the other end of the rods by locating the other end of the rod between three hot (T = 100°C) rolls, which were rotating according to the schematic cross-sectional Figure 8. The surfaces of the rolls were equipped with grooves with the thread profile. The partially threaded rods were cut to 30 mm long pieces and a flat head with the maximum diameter of the head 6 mm was upset to the non-threaded end of the rod by compression moulding in a hot mould (T >100°C).

A vertical osteotomy was done into the distal end of the femur of a rabbit into the cancellous bone area. The osteotomy was fixed with two screws which were manufactured with the above method. The fixation technique is shown schematically in an anteroposterial view (cross-section) in the Figure 9. After one year's follow-up time it was found that the osteotomy had healed well.

Example 10.

Three-dimensional braiding technique was applied to braid of Dexon[R] sutures (size USP 1) a tube-like preform with the

maximum diameter of 3 mm and with the wall thickness of 1 mm. The Figure 10 shows schematically the structure of the preform. Part of Dexon threads can be seen at the cut end of the preform.

A 40 mm long piece of preform was located into the cavity of an injection mould. The cavity had the form of a screw (length 40 mm, maximum therad diameter 4.5 mm, minimum thread diameter 3.2 mm, maximum diameter of the flat head 8 mm). The mould cavity of the mould was filled with polyglycolic acid (manufacturer Boehringer/Ingelheim, Germany) melt by applying the injection moulding technique (injection moulding machine: model Battenfeldt, Austria). The polyglycolide melt filled the cavity, the medullary cavity inside of the Dexon thread preform and covered also the Dexon preform. The cavity was cooled rapidly. The same mould was applied to manufacture screws of polyglycolide melt without Dexon thread braid reinforcement. The spiral reinforced screws (including the Dexon thread braid) showed the shear strength of 120 MPa and the non-reinforced screws showed the shear strength of 75 MPa.

Claims

1. Self-reinforced, absorbable surgical materials and/or implants (devices) and/or their parts and/or components, which can be implanted into the living tissue or on its surface for the purpose of e.g. to repair tissue damages, to join tissues or their parts to each other, to augment tissues or their parts, to separate tissues or their parts from each other and/or from their surroundings, and/or to conduct material between tissues or their parts and/or out of tissues or from the outside into the tissues,
c h a r a c t e r i z e d in that the reinforcing elements of self-reinforced materials and/or implants or their parts and/or components are wound at least partially around some axis penetrating the implant.

2. Materials, implants or their parts or components according to Claim 1, c h a r a c t e r i z e d in that their reinforcing elements are oriented molecular chains, molecule chain groups or their parts, oriented crystalline lamellae or spherulites, fibrils or their parts or corresponding morphological structural elements.

3. Materials, implants or their parts or components according to Claim 1 or 2, c h a r a c t e r i z e d in that their reinforcing elements are fibres, filaments, film fibres, threads, braids, non-vowen structures, networks, meshes, knits or vowen structures or corresponding fabrics.

4. Materials, implants or their parts or components according to any claim of Claims 1-3, c h a r a c t e r i z e d in that they include at least one hole, hollow or cavity, around which the reinforcing elements are wound at least partially.

5. A method to manufacture a material, implant or its part or component according to any claim of Claims 1-4,
c h a r a c t e r i z e d in that the reinforcing elements are located into a mould into which the melt of the matrix

polymer is injected or the reinforcing elements are transformed into such a physical state where they are bound at least partially to each other.

6. A method to manufacture a material, implant or its part or component according to any claim of Claims 1-4, c h a r a c t e r i z e d in that it is deformed to the desired shape with mechanical twisting, rolling, compression, stamping, drawing, upsetting or bending or by combining different deformation methods.

7. An implant, its part or component according to any claim of Claims 1-6, c h a r a c t e r i z e d in that it is a rod, nail, bolt, intramedullary nail, screw, clamp, tube, plate or rivet.

8. An intramedullary nail according to Claim 7, c h a r a c t e r i z e d in that it is at least partially hollow and/or in its wall is at least one longitudinal groove or hole, which has been formed by bending the wall inside and/or by splitting or perforating it at least partially.

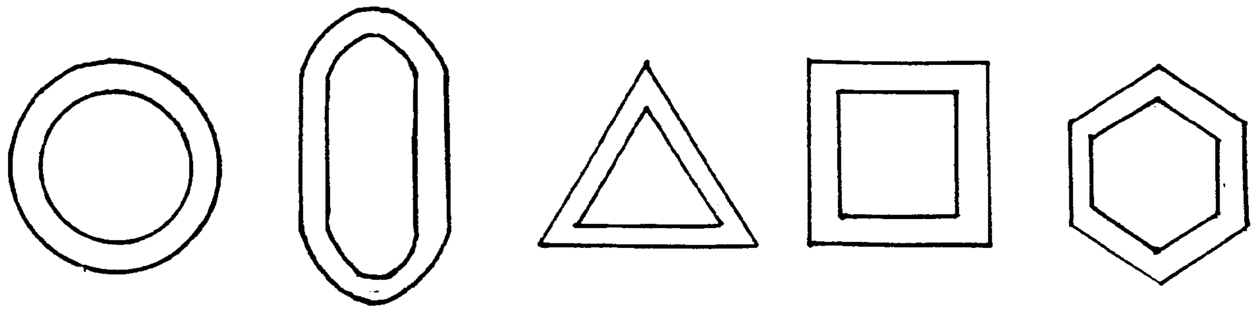


FIG 1

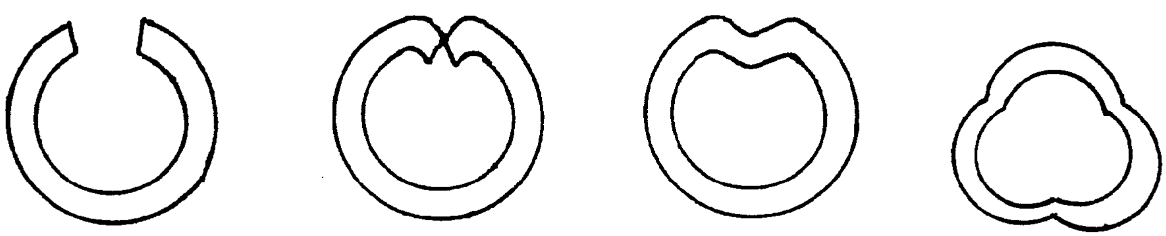
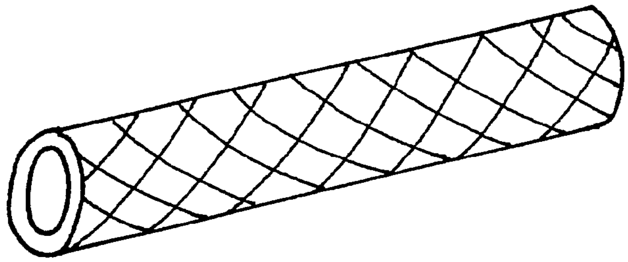
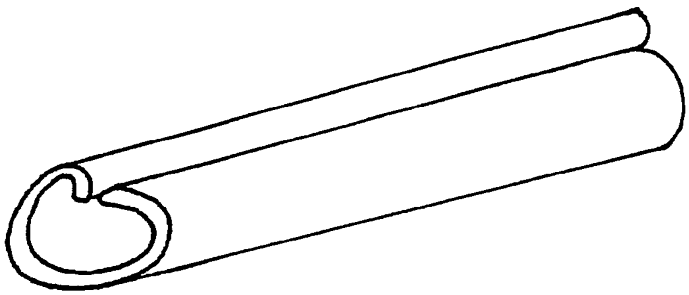


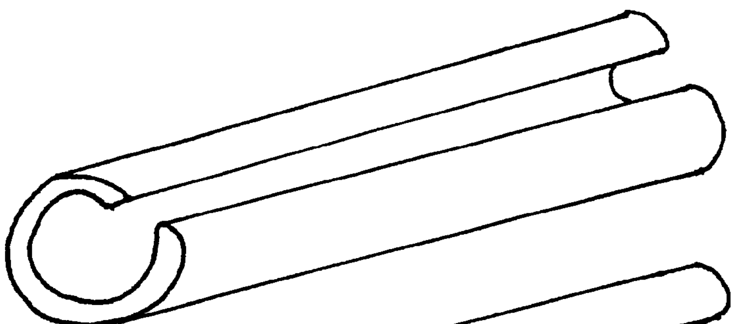
FIG 2



3a

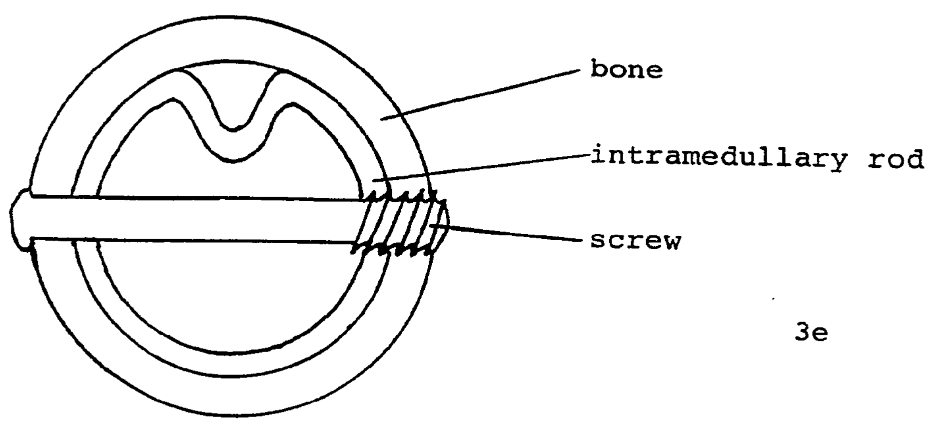


3b



3c

3d



3e

FIG 3

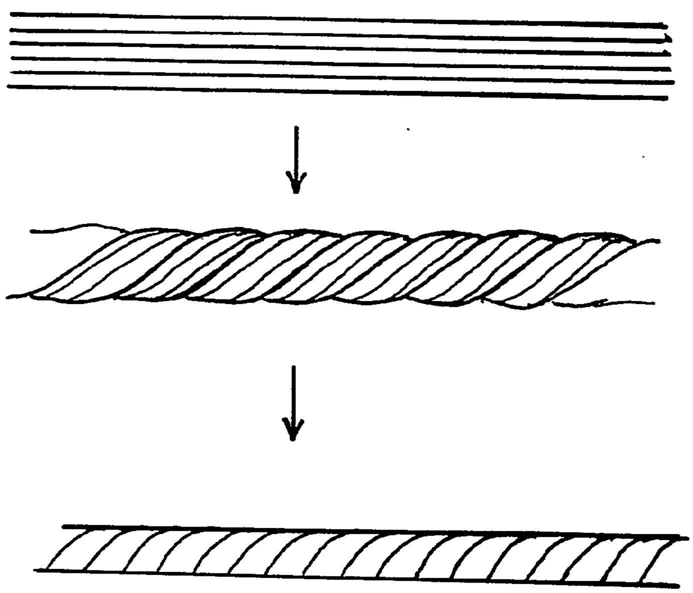


FIG 4

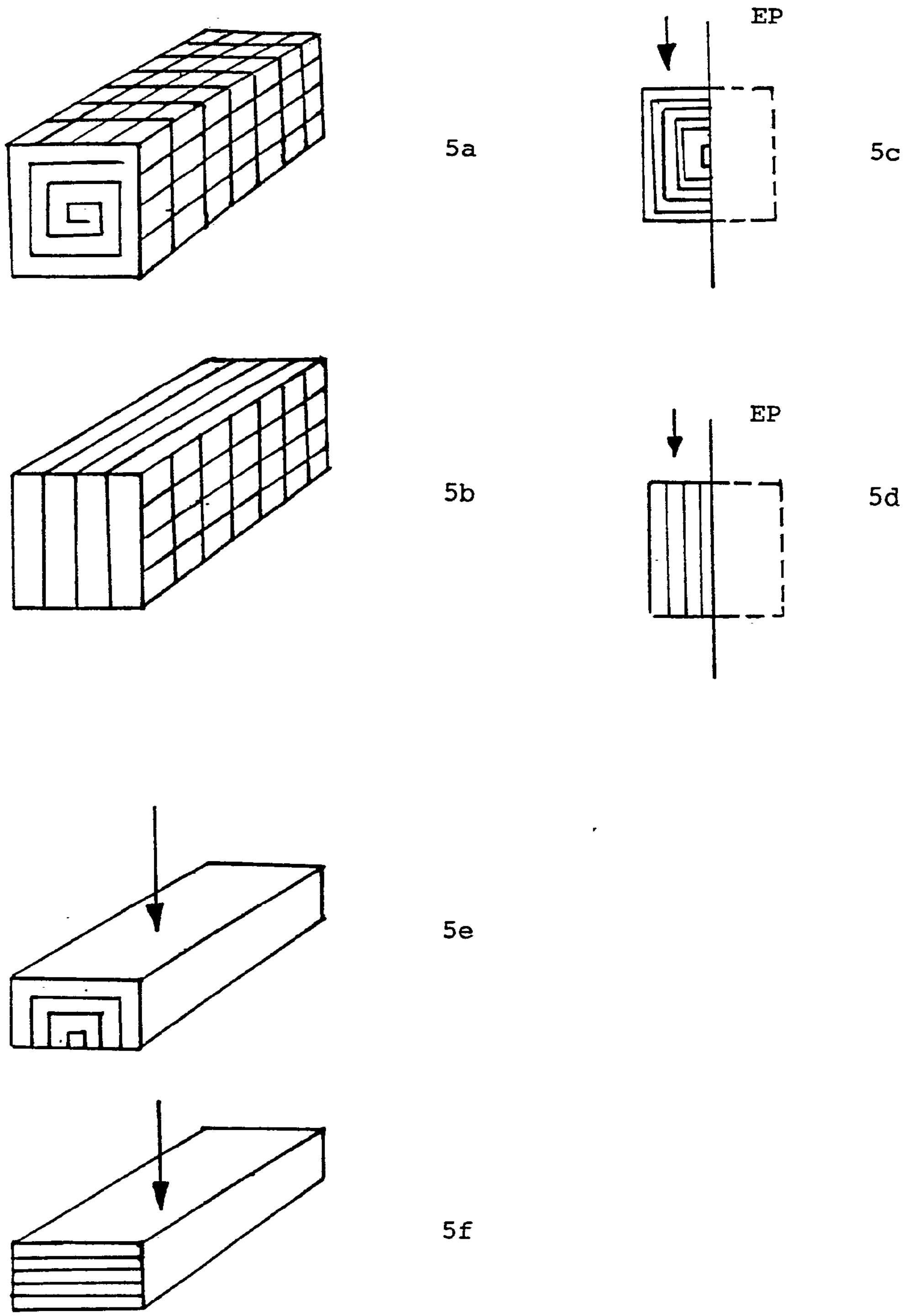


FIG 5

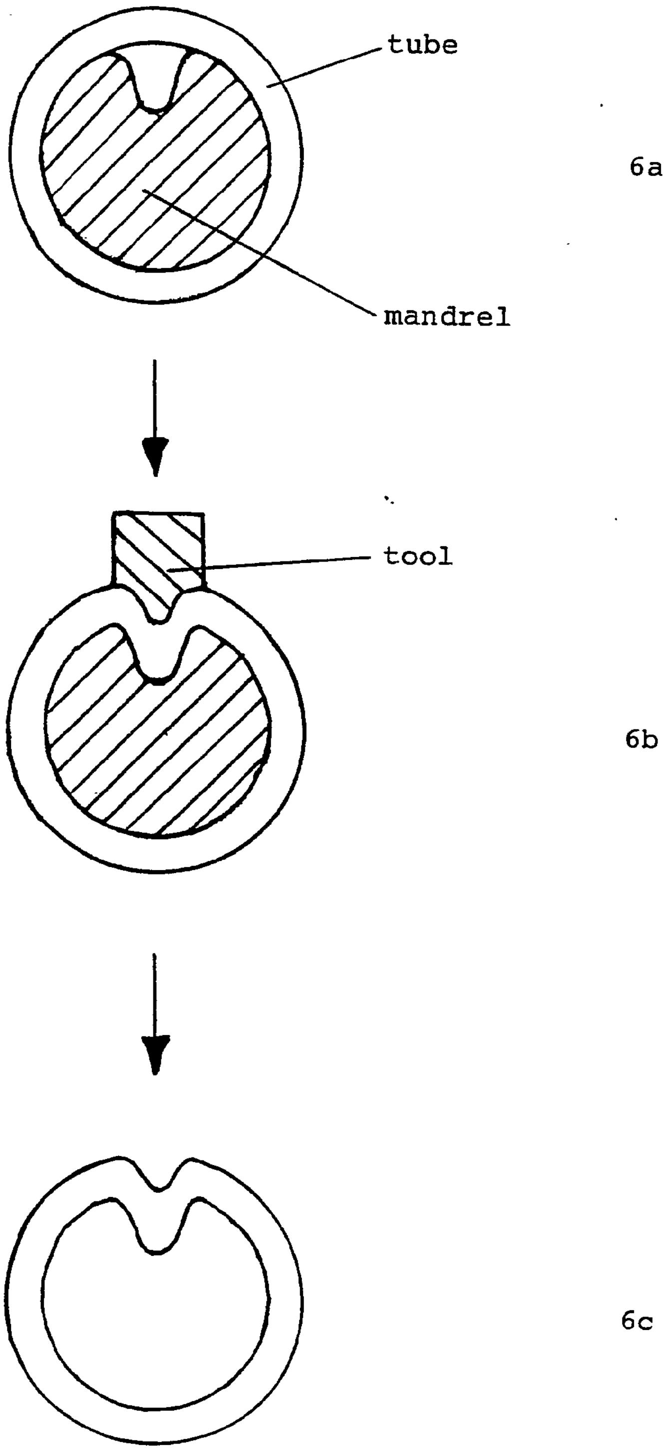


FIG 6

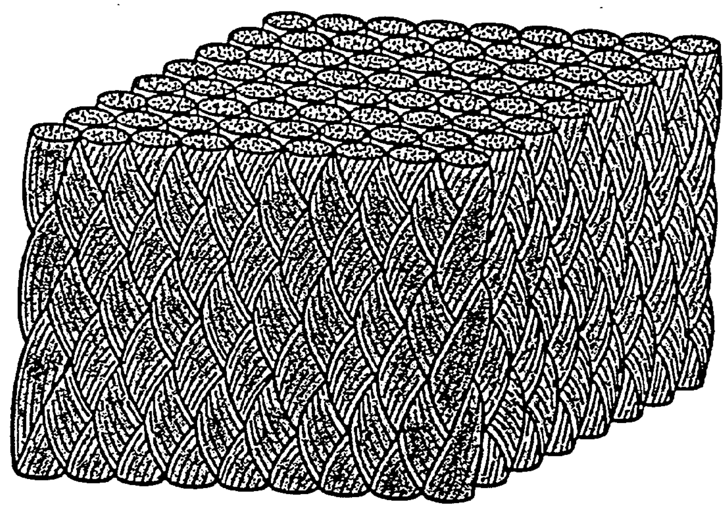


FIG 7

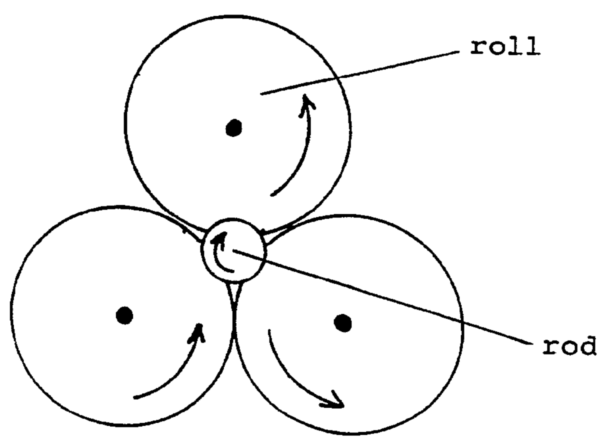


FIG 8

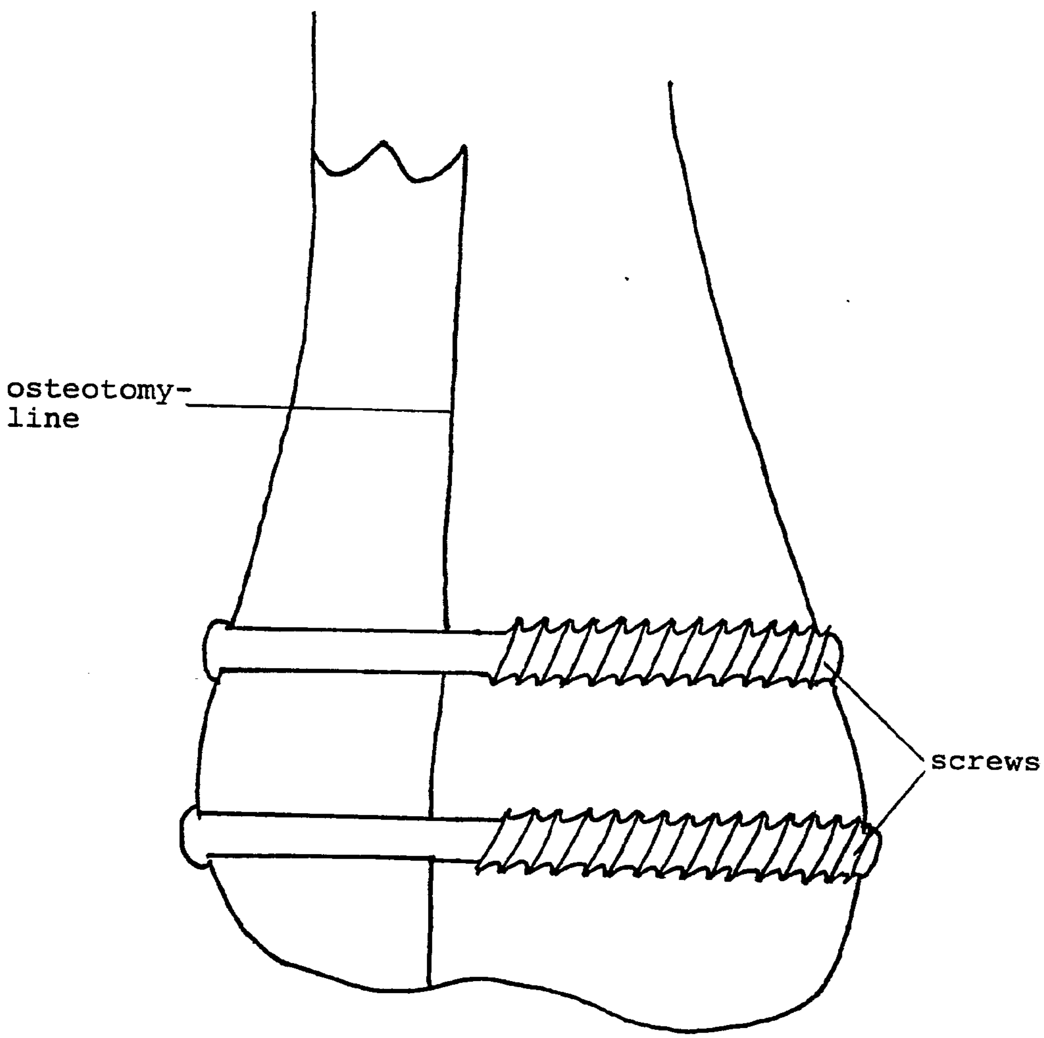


FIG 9

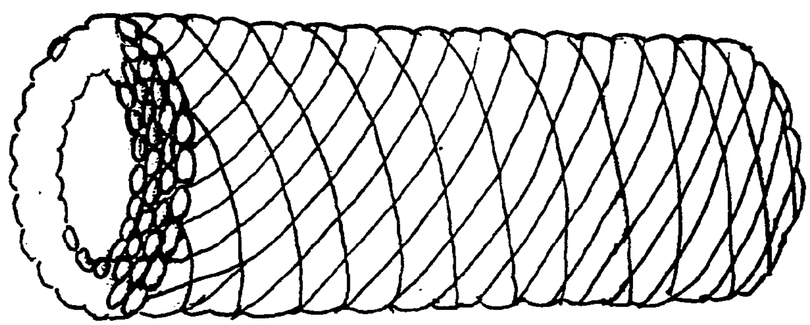


FIG 10

INTERNATIONAL SEARCH REPORT

International Application No PCT/FI 90/00113

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 F 2/08

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
IPC5	A 61 F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched[8]

SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document,[11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	DE, A1, 3042003 (H. REIMER) 15 July 1982, see the whole document --	1,3,5,6
Y	EP, A1, 0255408 (J-P LABOREAU) 3 February 1988, see column 2, line 36 - line 50; figures 1-6 --	1,3,5,6
Y	US, A, 4713070 (MANO) 15 December 1987, see the whole document --	1-6
Y	SE, B, 457692 (ASTRA MEDITEC AB) 23 January 1989, see figures 1-10; claims 1-11 --	1-4

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
17th July 1990	1990 -08- 01
International Searching Authority	**Signature of Authorized Officer**
SWEDISH PATENT OFFICE	C. Westberg C. Westberg

International Application No. PCT/FI 90/00113

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US, A, 4743257 (TÖRMÄLÄ ET AL) 10 May 1988, see the whole document --	1,2,5
A	US, A, 4329743 (ALEXANDER ET AL) 18 May 1982, see the whole document --	1,3
A	WO, A1, 8000533 (SCHWARZKOPF DEVELOPMENT CORPORATION) 3 April 1980, see figures 1,2; claims 1-6 --	7,8

International Application No. PCT/FI 90/00113

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers..........., because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers..........., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers..........., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 7-8 New items-improper multiple dependancy.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the the claims. It is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additonal fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional seach fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.PCT/FI 90/00113

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the Swedish Patent Office EDP file on 90-07-04
The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A1- 3042003	82-07-15	DE-A- 3038319	82-05-19
EP-A1- 0255408	88-02-03	FR-A- 2598315	87-11-13
US-A- 4713070	87-12-15	AU-B- 521190	82-03-18
		AU-D- 5327379	80-06-05
		BE-A- 879974	80-03-03
		CA-A- 1147109	83-05-31
		DE-A-C- 2947743	80-06-04
		FR-A-B- 2442713	80-06-27
		GB-A-B- 2037294	80-07-09
		JP-C- 1176078	83-11-14
		JP-A- 55075433	80-06-06
		JP-B- 58001656	83-01-12
		NL-A- 7908646	80-06-03
		SE-B-C- 435151	84-09-10
		SE-A- 7909867	80-05-31
		US-A- 4332035	82-06-01
		JP-C- 1313021	86-04-28
		JP-A- 55076648	80-06-09
		JP-B- 60037736	85-08-28
SE-B- 457692	89-01-23	AU-D- 1487388	88-10-10
		EP-A- 0349566	90-01-10
		SE-A- 8700969	88-09-10
		WO-A- 88/06872	88-09-22
US-A- 4743257	88-05-10	AU-B- 590270	89-11-02
		AU-D- 5688686	86-11-13
		CA-A- 1255451	89-06-13
		EP-A-B- 0204931	86-12-17
		JP-A- 61259674	86-11-17
		SU-A- 1496624	89-07-23
US-A- 4329743	82-05-18	CA-A- 1158806	83-12-20
		US-A- 4411027	83-10-25
		US-A- 4512038	85-04-23
WO-A1- 8000533	80-04-03	AT-A-B- 369255	82-12-27
		EP-A-B- 0008758	80-03-19